FILE: B-215739; B-216961 DATE: January 29, 1985

MATTER OF: Travenol Laboratories, Inc.

DIGEST:

Protest that item being procured will be used in a manner that is contrary to sound medical practice is not appropriate for consideration under GAO Bid Protest Procedures, since it relates more to Executive Branch policy than to the propriety of the procurement itself.

Travenol Laboratories, Inc. protests award under solicitation Nos. DLA120-84-R-1197, -1198, and DLA120-85-R-0046, issued by the Defense Logistics Agency's (DLA) Defense Personnel Support Center, Philadelphia, Pennsylvania, to procure vented intravenous (IV) injection sets. Travenol contends that the number of vented IV sets being procured greatly exceeds the government's actual requirements because Department of Defense (DOD) medical policy requires that the use of such sets be limited to the much smaller number of IV solutions procured in glass containers. We dismiss the protest.

DLA will procure a total of 1,609,920 vented IV sets under these three solicitations for distribution to various medical units throughout DOD. Travenol protested these solicitations prior to the closing date for receipt of proposals in each case and proposed unvented IV sets in lieu of the specified vented IV sets, even though it makes both types. DLA has withheld award pending resolution of these protests.

IV sets are used to administer separately procured IV solutions, which are prepackaged in either glass bottles or plastic bags. While glass bottles require a vented set because it contains a small valve which permits outside air to enter the bottle to displace the solution as it is used, vented sets will also work with plastic bag containers. Unvented IV sets, on the other hand, will work only with plastic bag containers, which collapse when the IV solution is withdrawn.

Apparently, vented sets, although designed for use with glass IV bottles, also work with plastic bag containers. According to Travenol, current medical research has shown that the use of vented sets with a plastic container unnecessarily exposes the patient to infection from contaminants in the outside air as well as to air embolisms (the entry of air into the bloodstream). Travenol warns that the failure to comply with what is now recognized as sound medical practice exposes the government and the manufacturer to claims by patients injured by the unnecessary introduction of outside air resulting from the use of vented IV sets with plastic containers.

Travenol asserts that despite this change in medical knowledge, the great bulk of the IV sets DLA purchases continue to be vented, even though just a small fraction of the IV solutions DLA purchases are packaged in glass containers. Based upon DLA's 1983 purchases of 141,800 units of IV solution packaged in glass containers, Travenol estimates that the 1,609,920 vented IV sets DLA will procure under these three solicitations represent a 11.4 year supply if they are used only with glass containers. 1/ Consequently, Travenol concludes, the protested solicitations do not reflect the government's actual requirements.

DLA responds that the DOD organizational unit responsible for overseeing medical practices, the Defense Medical Standardization Board, has looked into the guestion and agrees that sound medical practice requires that the use of vented IV sets be limited to glass containers. DLA advises that appropriate steps are being taken within DOD to implement this guidance by revision of federal supply catalogs, supply bulletins, and related documents to apprise medical units of the intended use of vented IV sets. Meanwhile, DLA argues, the quantities of vented IV sets being procured are urgently needed to fill substantial DOD back orders, which are currently being met by direct vendor purchase at premium cost.

Our Bid Protest Procedures require that a party be "interested" for its protest to be considered. 4 C.F.R.

^{1/} Alternatively, the continued use of vented sets with plastic IV bag containers would deplete this supply within a matter of months.

§ 21.1(a) (1984). In determining whether a protester satisfies the interested party criterion, we examine the degree to which the asserted interest is both established and direct. Pascua Yaqui Tribe, B-214471, July 16, 1984, 84-2 CPD ¶ 50. In making this evaluation, we consider the nature of the issues raised and the direct or indirect benefit or relief sought by the protester. Kenneth R. Bland, Consultant, B-184852, Oct. 17, 1975, 75-2 CPD ¶ 242.

Here, the protester deliberately submitted a non-conforming offer even though it admittedly markets conforming items in the normal course of business, and the protester's competitor did in fact submit a conforming offer. Further, Travenol's asserted economic interest in the procurement, that it will be exposed to potential claims if it sells conforming items to DLA with knowledge of possible misuse, is remote to the point of being speculative. It is our opinion that Travenol does not have a sufficient interest to protest the issuance of the solicitations in question.

Further, the relief Travenol seeks is beyond the scope of our bid protest function because it concerns DOD's medical policies and its enforcement of those policies. In this regard, Travenol would use the procurement system to compel DOD medical personnel to limit their use of vented IV sets to glass bottles by cutting off substantially all purchases of vented IV sets. Laudable as this objective may be in light of Travenol's assertion that sound medical practice requires that the use of vented IV sets be so limited, the matter relates primarily to DOD's management of its medical activities, a question we will not consider under the bid protest functions. See Crown Laundry and Cleaners, Inc., B-213796, et al., May 9, 1984, 84-1 CPD ¶ 516 and cases cited therein; 43 Comp. Gen. 217, 221 (1963).

Nevertheless, because of the significance of the issue Travenol raises and DOD's agreement from the standpoint of sound medical practice, we are suggesting to the Secretary of Defense that DLA's determination to proceed with the procurement of some 1.6 million vented IV sets be reconsidered.

The protest is dismissed.

Comptroller General of the United States